(6)

No. 05-1006

In the Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

SUPPLEMENTAL BRIEF FOR PETITIONERS

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CORPORATE DISCLOSURE STATEMENT

The parent company of Apotex Inc. is Apotex Pharmaceutical Holdings, Inc. The parent company of Apotex Corp. is Apotex Holdings, Inc. There is no publicly-held corporation that owns 10% or more of either Apotex Inc. or Apotex Corp.

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SUPPLEMENTAL BRIEF FOR PETITIONERS

Apotex submits this supplemental brief, pursuant to Rule 15.8 of this Court's rules, in response to Pfizer's supplemental brief and suggestion of mootness.

STATEMENT OF THE CASE

The "factual developments" discussed in Pfizer's supplemental brief do not render this appeal moot or any less worthy of this Court's review. On the contrary, the underlying dispute between Apotex and Pfizer—regarding the improper application of the Federal Circuit's so-called "reasonable apprehension" test to the Hatch-Waxman declaratory judgment mechanism—remains very much a live controversy of critical importance to Apotex, the generic pharmaceutical industry, and the public that relies upon that industry to bring affordable medicines to market.

Apotex brought this declaratory judgment suit to alleviate the enormous harm that it was suffering, and continues to suffer, by virtue of Pfizer's conduct and refusal to resolve a legitimate patent dispute. Apotex's harm includes its inability to obtain approval of its non-infringing generic product and compete in the market *and* the debilitating uncertainty associated with potentially huge infringement damages. After two-plus years of litigation, Pfizer now seeks to moot this case with an unsolicited covenant not to sue. The Court should reject Pfizer's transparent attempt to manipulate this Court's jurisdiction and insulate the favorable decision below from review.

First, Apotex retains a cognizable interest in the outcome of this case notwithstanding Pfizer's strategically-timed covenant and Teva's generic product launch. The covenant does nothing to alleviate the harm caused by Apotex's inability obtain the approval needed to enter the market, as it is entitled to do. Nor does Pfizer's carefully-

worded covenant apply to Apotex's suppliers and customers, without whom there is no market for Apotex's product.

Second, even if Apotex's product is approved 180 days after Teva's launch, Pfizer's voluntary conduct does not moot this appeal because Pfizer cannot satisfy its formidable burden of showing that its conduct will not recur. This very same dispute already has occurred between Apotex and Pfizer with respect to the drug Accupril®. There, too, Pfizer attempted to manipulate the reviewing court's jurisdiction and insulate a favorable decision from review by providing Apotex with an unsolicited covenant on the eve of argument before the Federal Circuit. Moreover, this same dispute will occur again between Apotex and Pfizer regarding the drug Lipitor®. Thus, the underlying dispute here is not the rare, patent-specific event that Pfizer portrays it to be, but one that continues to plague Apotex and other generic companies.

Third, even if Pfizer's covenant and Teva's launch render this *particular* case moot, this dispute nonetheless falls squarely within the well-known "capable of repetition, yet evading review" exception to the mootness doctrine. The dispute already has occurred twice between Apotex and Pfizer, and undoubtedly will again. What's more, it will be too short in duration for meaningful review by this Court—Pfizer will see to that. The Court, therefore, should reject Pfizer's suggestion of mootness and grant the petition.

SUPPLEMENTAL REASONS FOR GRANTING THE PETITION

I. This Appeal Is Not Moot Because Apotex Retains A Legally Cognizable Interest In Its Outcome.

A case is moot "when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *City of Erie v. Pap's A.M.*, 529 U.S. 277, 287 (2000). Neither is true here. The FDA continues to delay Apotex's approval based on an exclusivity period that

should have been triggered *years* ago. Pfizer's covenant does nothing to alleviate this enormous harm.

But even after Apotex's generic product is approved upon expiration of Teva's exclusivity, the threat and potential for infringement liability remains for Apotex's customers and suppliers. Pfizer's covenant applies only to Apotex, and does not constitute an admission that the patent is invalid or not infringed by Apotex's generic product. The covenant does not apply to Apotex's customers, who may opt instead to purchase the product from another company, rather than undertake the risk of patent infringement liability. Only a judgment of non-infringement or invalidity can alleviate this harm and risk. *See Minnesota Mining and Mfg. Co. v. Norton Co.*, 929 F.2d 670, 673-74 and n.4 (Fed. Cir. 1991) (noting that Declaratory Judgment Act sought to alleviate problems caused by threat of infringement liability to 3M and its customers, and rejecting argument that threats to 3M's customers did not cause harm to 3M). Thus, Apotex retains a legally cognizable interest in the outcome of this litigation even after its generic product is approved.

II. Pfizer Cannot, Through Voluntary Conduct, Manipulate This Court's Jurisdiction To Insulate A Favorable Decision From Review.

"A case might become moot if subsequent events made it absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 189 (2000); *accord United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953). But a "defendant's voluntary cessation of allegedly unlawful conduct ordinarily does not suffice to moot a case." *Friends of the Earth*, 528 U.S. at 174; *City of Mesquite v. Aladdin's Castle*, 455 U.S. 283, 289 (1983) (same). "If it did, the courts would be compelled to leave the defendant . . . free to return to his old ways." *Friends of the Earth*, 528 U.S. at 189. A "defendant claiming that its

voluntary compliance moots a case bears the formidable burden of showing that it is absolutely clear the allegedly wrongful behavior could not reasonably expected to recur." *Id.* at 190; *see also Adarand Constructors v. Slater*, 528 U.S. 216, 222 (2000) (same). Here, Pfizer cannot satisfy its formidable burden because its wrongful behavior will recur absent review by this Court. Indeed, this case is not the first time that this dispute has occurred between Apotex and Pfizer, nor will it be the last.

In 2003, Apotex filed a declaratory judgment action in an effort to obtain patent certainty and approval of its generic equivalent of Pfizer's Accupril® after Pfizer delayed filing suit in order to delay Apotex's approval. *See* Addendum at ¶ 5. A district court granted Pfizer's motion to dismiss the suit for lack of a case or controversy because Pfizer itself refused to file suit. *See TorPharm, Inc. v. Pfizer, Inc.*, No. Civ. 03-990, 2004 WL 1465756 (D. Del. June 28, 2004). On appeal, upon learning that the reviewing panel included two judges (Mayer, J. and Gajarsa, J.) who previously had expressed the view that a case or controversy exists in this circumstance, Pfizer precluded review by the Federal Circuit by sending Apotex an unsolicited covenant. *See* Addendum at ¶ 5. Pfizer did so only after it had delayed Apotex's approval for as long as it could without risking appellate review of a decision in its favor. *See id.*

Significantly, the very same dispute between Apotex and Pfizer will occur again with respect to Pfizer's Lipitor®. *See* Addendum at ¶¶ 6-12. Pfizer already has obtained a judgment of infringement on the basic patent against the first generic company to file a paragraph IV ANDA challenging all of the Orange Book-listed patents. *Id.* at ¶ 8. This means that the first-filer cannot go to market until the basic patent (and its pediatric exclusivity) expire on September 24, 2009. *Id.* But because Pfizer did not assert several later-expiring patents, the approval of all other generic applicants will be

delayed, both by the first-filer's exclusivity (see 21 U.S.C. § 355(j)(5)(B)(iv)), and the possibility of potentially catastrophic infringement damages on those patents. *Id.*

Apotex has developed its own generic Lipitor® and intends to submit an ANDA shortly. *See* Addendum at ¶ 9. Apotex intends to launch its generic product in September 2009, once the basic patent expires, provided that it can obtain patent certainty on the unasserted Pfizer patents. *Id.* Without court decisions on those patents, Apotex's approval, as well as the approval of any other generic applicants, will be delayed well beyond the expiration of the basic patent. *Id.* As with Accupril® and Zoloft®, however, Pfizer will have no incentive to, and likely will not, sue Apotex, precisely because Pfizer can delay generic competition longer and create a bottleneck by delaying suit and avoiding a court decision on the later-expiring patents. *Id.* at ¶¶ 10-11. As with Accupril® and Zoloft®, Apotex will have no choice but to file a declaratory judgment action against Pfizer in order to get prompt approval and patent certainty.

Thus, Pfizer cannot show that its conduct will not recur, let alone that it is "absolutely clear" that such conduct will not recur. As a result, Pfizer's suggestion that there "is little reason to assume" and no "realistic possibility" that Apotex will face this situation again where a brand company uses a covenant not to sue to manipulate the Court's jurisdiction is disingenuous, if not absurd.

In *Pap's*, after prevailing below in a challenge to a public indecency ordinance, Pap's attempted to moot the case and preclude review by this Court with an affidavit stating that it had ceased the allegedly offending conduct (*i.e.*, the operation of a nude dancing establishment). *See* 529 U.S. at 287. Pap's argued that the case therefore was moot because the outcome of the case "will have no effect upon Respondent." *Id.* This Court disagreed, holding that Pap's voluntary cessation did not moot the case. *See id.* The

Court also held that the city had an ongoing injury because it could not enforce its ordinance, and that the availability of relief allowing the city to do so was "sufficient to prevent the case from being moot." *Id.* at 288. The Court also acknowledged that *Pap's* did not present "a run of the mill voluntary cessation case" because it was the party "who, having prevailed below, now seeks to have the case declared moot." *Id.* The Court thus held that its "interest in preventing litigants from attempting to manipulate the court's jurisdiction to insulate a favorable decision from review further counsels against a finding of mootness here." *Id.*

Here, nothing prevents Pfizer from engaging in the same conduct with Apotex, or another generic company, that gave rise to this dispute. Indeed, Pfizer already has done so with respect to Accupril® and Zoloft®. Reversing the decision below would allow Apotex to bring a declaratory judgment claim to prevent such harm in the future. Moreover, it is Pfizer, who, "having prevailed below, now seeks to have the case declared moot." *Pap's*, 529 U.S. at 288. As in *Pap's*, this Court's interest in preventing such manipulation counsels against a finding of mootness. Nothing in the cases Pfizer cites suggests that a party that prevailed below can so blatantly manipulate the Court's jurisdiction to insulate a favorable decision from review.

III. Alternatively, This Case Falls Squarely Within The "Capable Of Repetition, Yet Evading Review" Exception To The Mootness Doctrine.

A case is not moot if the "underlying dispute between the two parties is one capable of repetition, yet evading review." *Gannett Co. v. DePasquale*, 443 U.S. 368, 377 (1979). This exception applies where "(1) the challenged action was in its duration too short to be fully litigated prior to its cessation or expiration, and (2) there was a reasonable

expectation that the same complaining party would be subjected to the same action again." *Id.*

First, the same underlying dispute—*i.e.*, application of the Federal Circuit's "reasonable apprehension" test to a declaratory judgment action filed by a generic company—is certainly capable of repetition. As set forth in Section II, *supra*, this same dispute happened before between the same parties in Accupril®, and in all likelihood, will happen again between these parties over Lipitor®. *See* Addendum at ¶ 6. The same dispute also will arise between Apotex and other brand companies on other products. *See id.* at ¶¶ 13-14.

Pfizer's argument that the underlying dispute can never happen again because it has vowed never to sue Apotex on *this particular patent* over *this drug* reads this Court's precedent far too narrowly. Indeed, if that were the law, the "capable of repetition, yet evading review" exception could *never* apply to any aspect of a patent dispute. But this Court has never narrowed its application in this manner. In fact, this Court explicitly has held that the same controversy can recur when different subject matter or different parties are involved.

For example, in a long line of cases relating to court orders restricting media access to criminal proceedings, this Court recognized that the complaining parties may be injured by other, future orders concerning different proceedings or issued by other courts. The Court repeatedly has held that such situations qualify as "capable of repetition." *See Nebraska Press Ass'n v. Stuart*, 427 U.S. 539, 546 (1976) ("[t]he dispute between the State and the petitioners who cover events throughout the State" is "capable of repetition" because state prosecutors are authorized to seek restrictive orders in appropriate cases); *Ganne[illegible]* U.S. at 377-78 ("it is reasonably to be expected that t[illegible]petitioner, as publisher of two New York newspapers, will be subjected to similar closure orders entered by New York courts"); *Globe*

Newspaper v. Superior Court, 457 U.S. 596, 603 (1982) (it could reasonably be assumed that newspaper publisher would someday be subjected to further orders excluding it from courtrooms during testimony in other sex-offense trials); *Richmond Newspapers, Inc. v. Virginia*, 448 U.S. 555, 563 (1980) (noting that "other trials may be closed by other judges," making appeal of order excluding public and press from courtroom "capable of repetition, yet evading review"); *Press-Enterprise Co. v. Superior Court of Ca.*, 478 U.S. 1, 6 (1986) (controversy was "capable of repetition, yet evading review" because it could "reasonably be assumed that petitioner will be subjected to a similar closure order").

The Court also has held that the same controversy, despite having different underlying facts, can be "capable of repetition" in other analogous situations. For example, in *Securities and Exchange Comm'n v. Sloan*, the SEC said that it would no longer issue suspension orders against the respondent like the order at issue. *See* 436 U.S. 103, 108 (1978). The Court did not declare the dispute moot, finding a "reasonable expectation" that respondent would be subject to other orders suspending trading in the future, given the respondent's behavior and that the respondent owned other securities on which trading might also be suspended. *See id.* at 109-10. And in *Roe v. Wade*, the Court noted that "[p]regnancy often comes more than once to the same woman, and in the general population, if man is to survive, it will always be with us. Pregnancy provides a classic justification for a conclusion of nonmootness." 410 U.S. 113, 125 (1973).

Here, even if Pfizer (or another brand company) refuses to sue Apotex (or another generic company) on a different patent related to a different drug, the same controversy would repeat itself. Apotex has shown that the same controversy already has occurred between Apotex and Pfizer with respect to Accupril®, and will do so again for

Lipitor®. Pfizer's assertion that the issues are "highly fact-bound" (Pfizer Supp. Br. at 4) is belied by the repeated recurrence of this dispute between Apotex and Pfizer.[1] Thus, the controversy here undoubtedly is "capable of repetition."

Second, the challenged action always will be too short in duration for meaningful review because Pfizer always can give a covenant not to sue. Pfizer's own conduct allows the Court to disregard Pfizer's arguments to the contrary. Notwithstanding Pfizer's assertions about valuable patent rights and patentees not lightly or frequently relinquishing them (Pfizer Supp. Br. at 5), Pfizer itself has used covenants in two disputes involving Apotex in order to insulate a favorable decision from review. Every case involving this jurisdictional issue will be "short-lived" if the defendant is allowed to simply cease the controversy of its own accord after receiving a favorable appellate decision.[2]

Pfizer's conduct is analogous to the court orders in the SEC and court sealing cases, in which the orders expired before this Court could review the underlying issues. *See Sloan*, 436 U.S. at 109-10; *Nebraska Press Ass'n*, 427 U.S. at 546; *Gannett*, 443 U.S. at 377-78; *Globe Newspaper*, 457 U.S. at 603; *Richmond Newspapers*, 448 U.S. at 563; *Press-Enterprise*, 478 U.S. at 6. Here, Pfizer can argue that the case "expired," in effect, only because Pfizer decided it should, just as the courts and the SEC set limits on the lengths of their orders in those cases. And as in the voluntary cessation cases, this Court's "interest in preventing

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[1] Pfizer's assertion that the "statutory scheme has been fundamentally altered for future cases" is not true. *See* Pfizer Supp. Br. at 4. The ability of a generic company to obtain a declaratory judgment is, in fact, even more critical under the amended statute. *See* Apotex Reply Br. at 2-4.

[2] Pfizer's own argument that, if necessary, it could have mooted the *Teva* case at any time with a unilateral covenant not to sue destroys its reliance on the prior *Teva* litigation for the proposition that the dispute is not too short in duration. *See* Pfizer Supp. Br. at 5.

litigants from attempting to manipulate the Court's jurisdiction to insulate a favorable decision from review" should prevent Pfizer from unilaterally controlling the duration of the controversy in order to attempt to moot this case. *Pap's*, 529 U.S. at 288. This issue, largely through Pfizer's own conduct, has certainly evaded review, and will continue to do so as long as the defendants like Pfizer control the duration of the case.

CONCLUSION

The Court should reject Pfizer's suggestion of mootness and grant Apotex's petition for a writ of certiorari.

Respectfully submitted,

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DECLARATION OF DR. BERNARD C. SHERMAN

I, DR. BERNARD C. SHERMAN, Ph.D., declare as follows:

1. I am the founder, Chairman and Chief Executive Officer of Apotex Inc. ("Apotex"), a Canadian-based pharmaceutical company that develops and manufactures quality generic medicines.

2. I have personal knowledge of the facts set forth herein, or believe them to be true based on my experience in the pharmaceutical industry and information I have received in the course of my duties, and am competent to testify to the same.

3. I submit this Declaration in response to Pfizer's supplemental brief and suggestion of mootness.

4. The underlying dispute between Apotex and Pfizer—regarding the Federal Circuit's application of its so-called reasonable apprehension test to the critical Hatch-Waxman declaratory judgment mechanism—already has occurred once between Apotex and Pfizer and I believe will recur again.

5. In 2003, Apotex filed a declaratory judgment action in an effort to obtain patent certainty and approval of its generic equivalent of Pfizer's Accupril®. A district court granted Pfizer's motion to dismiss the suit for lack of a case or controversy because Pfizer itself refused to file suit. On appeal, upon learning that the panel in the case included two judges (Mayer, J. and Gajarsa, J.) who had in previous cases expressed the view that a case or controversy exists in these circumstances, Pfizer attempted to preclude any meaningful review by the Federal Circuit by sending Apotex an unsolicited covenant not to sue—just as Pfizer has done in this case. Pfizer did so only after it had delayed Apotex's approval to the longest extent possible.

6. As with Pfizer's Accupril® in the prior case and Zoloft® here, the very same dispute between Apotex and Pfizer will occur again with respect to Pfizer's Lipitor®, the largest-selling prescription drug in the world today.

7. Pfizer has listed five (5) patents in FDA's Orange Book in connection with Lipitor®: U.S. Patent No. 4,681,893 ("the '893 patent"), expiring September 24, 2009 (with pediatric exclusivity to March 24, 2010); U.S. Patent No. 5,273,995 ("the '995 patent"), expiring December 28, 2010; U.S. Patent No. 5,686,104 ("the '104 patent"), expiring November 11, 2014; U.S. Patent No. 5,969,156

("the '156 patent"); and U.S. Patent No. 6,126,971 ("the '971 patent"), expiring January 19, 2013.

8. While the pertinent claim of the '995 patent has been held invalid, Pfizer already has obtained a judgment of infringement on the '893 patent against the first generic company to file a PIV ANDA challenging all of the Orange Book-listed patents. This means that the first-filer cannot go to market until the '893 patent (and its pediatric exclusivity) expire on September 24, 2009. But because Pfizer did not assert the later-expiring '104, '156 and '971 patents, the approval of subsequent generic ANDA applicants—even ones that have successfully designed around those patents—will be blocked and delayed, both by the first-filer's exclusivity, pursuant to 21 U.S.C. § 355(j)(5)(B)(iv), and the uncertainty associated with potentially catastrophic infringement damages on those patents.

9. Apotex has developed its own generic version of Lipitor® for which it intends to submit an ANDA shortly. Apotex intends to launch its generic product in September 2009 upon the expiration of the '893 patent, provided that Apotex can obtain patent certainty and court decisions on the unasserted Pfizer patents to clear the way for approval. Without court decisions on those patents, Apotex's approval, as well as the approval of any other generic applicants, will be delayed well beyond the expiration of the '893 patent.

10. As with Accupril® and Zoloft®, Pfizer will have no incentive to, and likely will not, sue Apotex, precisely because Pfizer can delay generic competition longer and create a bottleneck by delaying suit and avoiding any court decisions on the later-expiring '104, '156 and '971 patents.

11. In these circumstances, as with Accupril® and Zoloft®, Apotex will have no choice but to file another

declaratory judgment action against Pfizer in order to obtain approval of its product and patent certainty. This is the very same dispute that already occurred with respect to Accupril® and in the present case regarding Zoloft®. As before, Pfizer can attempt to manipulate the Court's jurisdiction yet again and preclude meaningful review by this Court by giving Apotex an unsolicited covenant not to sue.

12. The underlying dispute and circumstances of this case will continue to occur between Apotex and Pfizer as long as Pfizer is permitted to manipulate the Court's jurisdiction and insulate a favorable decision from review.

13. Furthermore, Apotex also has brought declaratory judgment claims against another brand company, Janssen, in connection with Apotex's attempt to market a generic version of Risperdal®. Janssen, like Pfizer, refused to bring suit against Apotex on the latest expiring listed patents. Once Apotex asserted its claims on these patents, Janssen moved to dismiss Apotex's declaratory judgment claims, citing, among other things, the Federal Circuit decision that Apotex asks this Court to review here.

14. Finally, Apotex has filed an ANDA for Trileptal®. Should Novartis Pharmaceuticals follow Pfizer's lead and attempt to delay approval of Apotex's ANDA by refusing to bring an infringement suit, Apotex will have no choice but to consider declaratory judgment claims in that situation as well.

15. The foregoing facts are true and correct as I verify and believe.

Dated this 14th day of September, 2006.

I, DR. BERNARD C. SHERMAN, hereby declare, under penalty of perjury under 28 U.S.C. § 1746 and the laws of the United States of America, that the foregoing Declaration is true and correct.

__/s/__Signature_____
DR. BERNARD C. SHERMAN